IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

United States of America, *et al.*, Plaintiffs, *ex rel.* Scarlett Lutz, *et al.*, Plaintiffs-Relators, v. Berkeley Heartlab, Inc., *et al.*, Defendants.	Civil Action No. 9:14-cv-00230-RMG (Consolidated with 9:11-cv-1593-RMG and 9:15-cv-2458-RMG) **ORDER and OPINION**

This matter is before the Court on the United States' motion to exclude Curtis Udell's expert testimony proffered by BlueWave Healthcare Consultants, Inc., Floyd Calhoun Dent, III, and Robert Bradford Johnson (collectively, "the BlueWave Defendants"). (Dkt. No. 443.) For the reasons set forth below, the motion to exclude is granted.

I. Background

The Government has filed a complaint in intervention against the BlueWave Defendants and Latonya Mallory alleging violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and the False Claims Act ("FCA"), 42 U.S.C. § 3729(a). (Dkt. No. 75.) The alleged FCA violations arise from BlueWave's marketing of laboratory tests for two laboratory companies, Health Diagnostic Laboratory, Inc. ("HDL") and Singulex, Inc. ("Singulex"), between 2010 and 2014. The Government has alleged that Defendants violated the FCA when they engaged in multiple kickback schemes to induce physicians to refer blood samples to HDL and Singulex for large panels of blood tests, many of which were medically unnecessary. For example, the Government alleges that Defendants offered and facilitated the payment of

processing and handling ("P&H") fees to physicians to induce referrals in violation of the AKS and FCA.

II. Legal Standard

a. *Daubert*

Under Rules 104(a) and 702, "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). The trial court must ensure that: (1) "the testimony is the product of reliable principles and methods"; (2) "the expert has reliably applied the principles and methods to the facts of the case"; and (3) the "testimony is based on sufficient facts or data." Fed. R. Evid. 702(b) - (d). "This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid," *Daubert*, 509 U.S. at 592-93, and whether the expert has "faithfully appl[ied] the methodology to facts," *Roche v. Lincoln Prop. Co.*, 175 F. App'x 597, 602 (4th Cir. 2006). To make this determination, courts consider several factors including: (1) "whether a theory or technique . . . can be (and has been) tested"; (2) "whether the theory or technique has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the theory or technique has garnered "general acceptance." *Daubert*, 509 U.S. at 593-94; *accord United States v. Hassan*, 742 F.3d 104, 130 (4th Cir. 2014). However, these factors are neither definitive nor exhaustive, *United States v. Fultz*, 591 F. App'x 226, 227 (4th Cir. 2015) (quoting *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003)), and "merely illustrate[] the types of factors that will bear on the inquiry," *Hassan*, 742 F.3d at 130 (quoting *Crisp*, 324 F.3d at 266).

Courts have also considered whether the "expert developed his opinions expressly for the purposes of testifying," *Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158 (4th Cir. 1998), or

through "research they have conducted independent of the litigation," *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (on remand), and whether experts have "failed to meaningfully account for . . . literature at odds with their testimony." *McEwen v. Balt. Wash. Med. Ctr. Inc.*, 404 F. App'x 789, 791 (4th Cir. 2010).

Rule 702 also requires courts "to verify that expert testimony is 'based on sufficient facts or data.'" *EEOC v. Freeman*, 778 F.3d 463, 472 (4th Cir. 2015) (quoting Fed. R. Evid. 702(b)). Thus, "trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable." *Id.* The court may exclude an opinion if "there is simply too great an analytical gap between the data and the opinion offered." *Id.* "The proponent of the [expert] testimony must establish its admissibility by a preponderance of proof." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

The Court is mindful that the *Daubert* inquiry involves "two guiding, and sometimes competing, principles." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). "On the one hand, . . . Rule 702 was intended to liberalize the introduction of relevant expert evidence," *id.*, and "the trial court's role as a gatekeeper is not intended to serve as a replacement for the adversary system." *United States v. Stanley*, 533 F. App'x 325, 327 (4th Cir. 2013), (citing Fed. R. Evid. 702 advisory committee's note), *cert. denied*, 134 S. Ct. 1002 (2014). On the other hand, "[b]ecause expert witnesses have the potential to be both powerful and quite misleading,' it is crucial that the district court conduct a careful analysis into the reliability of the expert's proposed opinion." *Fultz*, 591 F. App'x at 227 (quoting *Cooper*, 259 F.3d at 199).

b. Fair Market Value

Both parties have relied on the definition for fair market value included in the Stark Regulations. Fair market value is defined therein as

> [V]alue in arm's-length transactions, consistent with the general market value. "General market value" means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.

42 C.F.R. § 411.351; *see also U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 675 F.3d 394, 398 n.7 (4th Cir. 2012). While there is "no rule of thumb that will suffice for all situations," The Centers for Medicare & Medicaid Services ("CMS") has indicated that it "intend[s] to accept any method [to determine FMV] that is commercially reasonable and provides [the agency] with evidence that the compensation is comparable to what is ordinarily paid . . . by parties in arm's length transactions who are not in a position to refer to one another." *Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships*, 66 F. R. 856-01, 944, 2001 WL 7418 (Jan. 4, 2001); *Renal Physicians Ass'n v. Dep't of Health & Human Servs.*, 422 F. Supp. 2d 75, 77-78, 84 (D.D.C. 2006), *aff'd sub nom. Renal Physicians Ass'n v. U.S. Dep't of Health & Human Servs.*, 489 F.3d 1267 (D.C. Cir. 2007); *U.S. ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602, 629–30 (W.D. Pa. 2010).

III. Relevant Facts

a. CPT Code 99000

Medicare applies the Medicare Physician Fee Schedule ("MPFS") to determine reimbursement for physicians' services. The MPFS uses a standardized coding system called the

Current Procedural Terminology ("CPT") that identifies each service and the appropriate reimbursement for that service. The CPT codes are published annually by the American Medical Association.

CPT Code 99000 is the code used by physicians to capture the processing and handling services completed by the physician's office to prepare a specimen for transport to a laboratory (i.e., centrifuging, separating serum, labeling specimens, packing specimens, or filling out forms). Code 99000 is an adjunct code, meaning that it cannot be reported independently but must be reported in conjunction with a code for one of the basic services rendered to the patient. During the relevant period, 2009 through 2014, Code 99000 was "bundled" with the physician reimbursement code for Evaluation and Management ("E&M") services. The E&M code covers the costs associated with a patient's visit to an office and evaluation by a physician.

For example, during an office visit with a patient, a physician may identify the need for a blood panel, collect a blood sample from the patient, and prepare that sample for transport to a laboratory. That physician would bill Medicare for reimbursement using the E&M code for an office visit. Although the physician would also record Code 99000 to account for the preparation of the blood sample, Medicare would not separately reimburse him or her for those P&H services because it considers the P&H costs to be "subsumed by the payment for the services to which they are incident."[1]

b. Curtis Udell's Fair Market Value Opinion

The Government alleges that Defendants offered and facilitated the payment of P&H fees to physicians to induce referrals in violation of the AKS and FCA. The P&H fees – which purportedly covered physicians' processing, handling and shipping of blood specimens for

[1] CMS Fee Schedule Administration and Coding Requirements available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf.

laboratory diagnostic testing – were paid pursuant to written P&H fee agreements between HDL and Singulex (hereinafter "the laboratories") and the physicians or their practices. Pursuant to written sales agreements with the two labs, BlueWave marketed the laboratories' testing services to physicians.

The United States has proffered Kathy McNamara to provide an expert opinion about the Fair Market Value (FMV) of those P&H fees. The BlueWave Defendants have proffered Curtis Udell's expert testimony in response to McNamara's report. Udell relied on a "charge-based methodology" to develop his opinion that the P&H fees paid by the laboratories were consistent with the FMV of these services.[2] (Dkt. No. 443-1.) He concluded that HDL's payments for P&H services were "in-line" with the "national physician charge values billed for venous collection and P&H services"; "payment data for venous collection code CPT 36410"; and "physician's expectation for payment – as expressed as a billed line item." (Dkt. No. 443-1 at 4.) The Government argues that a charge-based methodology cannot produce a reliable conclusion about the FMV of the P&H services. This Court agrees. Udell's testimony is inadmissible because it is not the product of a reliable methodology and is not based on sufficient facts or data.

The BlueWave Defendants defend Udell's charge-based methodology on two primary grounds. First, they argue that there is no default rule for calculating FMV and there is "nothing in the statute, regulation, or rulemaking requires FMV calculations to be based on "transactions," rather than simply charges, costs, or price." (Dkt. No. 475 at 6.) Second, they argue that the Government has actually endorsed Udell's charge-based methodology.

[2] Udell acknowledged that he incorrectly included the term "commercial reasonableness" in his report and that his analysis is a FMV analysis. (Dkt. No. 443-2 at 10-11.)

IV. Discussion

a. A Charge-Based Methodology is Not a Reliable Approach to Determining the FMV of Physician Services

While there is no default rule for calculating FMV, the lack of a one-size-fits-all rule does not mean that anything goes. The BlueWave defendants claim that the Court should allow Udell's testimony because no Court has rejected a charge-based methodology for determining FMV in the FCA context.

To begin, it is no secret that the sticker prices of services listed in physician bills and hospital chargemasters are totally unmoored from the reality of arm's-length transactions actually taking place in the marketplace. *What's The Cost?: Proposals To Provide Consumers With Better Information About Healthcare Service Costs*, before the Committee On Energy And Commerce House Of Representatives, 109th Cong. (2006) (Statement of Dr. Gerald F. Anderson, Johns Hopkins, Bloomberg School Of Public Health, Health Policy And Management) ("List prices are established by the hospitals and physicians without any market constraints. Too often list prices have no relationship to the prices that are actually being paid by insurers."); George A. Nation III, *Determining the Fair and Reasonable Value of Medical Services: The Affordable Care Act, Government Insurers, Private Insurers and Uninsured Patients*, 65 Baylor L. Rev. 425, 429-430 (2013) ("[C]hargemaster or list prices . . . are grossly inflated because they are set to be discounted rather than paid. . . . [T]hey certainly do not represent the usual price actually paid for the listed goods and services.").

But the Court need not rely on this widely reported phenomenon. Experts from both parties have conceded that insurers and Medicare do not pay physician charges, and physicians do not expect to receive their charges. The Government has offered an in-depth explanation from

Kathleen McNamara as to why physicians set their fees higher than the Medicare fee schedule – that is – higher than what they actually expect to receive in reimbursement from Medicare.

> Pursuant to statute, and subject to exceptions not applicable here, Medicare payments for physicians' services are (and were during the relevant period) the lesser of the Medicare Physician Fee Schedule (MPFS) amount and the physician's actual charge for the service. Thus, if MPFS establishes a payment of $100 for a service, a physician who charges $150 or $15,000 for the service would receive at most $100 from Medicare for the service. In my experience, most other insurance payors also pay the lesser of their fee schedule for physician services and the physician's actual charge.
>
> As a result, prudent physician practices set their charges higher than expected fee schedule payments. For this reason, it has been my experience that physician practices often set their charges at 200%-500% of the MPFS amounts.

(Dkt. No. 443-3 at 3.) Although Udell insists in his report that physician charges represent physicians' expectations of payment (Dkt. No. 443-1 at 7), he agreed with McNamara's analysis when he stated, during his deposition, that physicians set their charges higher than both Medicare and private insurers will actually pay. (Dkt. No. 443-2 at 15.)

First, Udell acknowledged that physicians submit their retail charges to Medicare with the knowledge that Medicare is not allowed to pay them any amount above the Medicare fee schedule. (Dkt. No. 443-2 at 24.) Udell explained that physicians may nudge their fees even higher than necessary to clear the current Medicare fee schedule rate because: (1) physicians "are not going to set their fee at the Medicare rate because then they would be billing at a rate that was below what somebody else may pay, so they want one fee schedule that they can apply to everybody" (Dkt. No. 443-2 at 23); and (2) "because the Medicare fee schedule changes every year" and for physicians to change their fees to match an increase in the fee schedule, they "would have to get their staff to make those changes January 1 and who wants to work December 31st, nobody." (Dkt. No. 443-2 at 18.)

With regard to private insurers, Udell explained that physicians "don't want to leave money on the table" so set their charges deliberately above what they expect an insurance company is willing to pay (Dkt. No. 443-2 at 16), but "typically" sign contracts with private insurers in which they agree to accept a fee that is lower than their charge. (Dkt. No. 443-2 at 23.) Finally, Udell acknowledged that his own practice is paid only about 68% of the fees it charges. (Dkt. No. 443-2 at 24.) He agreed that "as a consultant, if you go into a physician practice and they are getting 100% of their charges you know something is wrong" and that his "ultimate recommendation" in that case would be for the practice to raise its fees. (Dkt. No. 443-2 at 16.)

Udell takes issue with McNamara's characterization of physician fee-setting as "arbitrary" (Dkt. No. 443-2 at 18) when, according to him, "a great deal of effort . . . science. . . and thought processing. . . goes into developing these fee schedules." (Dkt. No. 443-2 at 18.) The Court agrees that physician fee-setting may not be totally arbitrary, but Udell's explanations bolster the sole conclusion that physicians deliberately set their fees higher than the amount they either expect to receive and do in fact receive to ensure that no money is left on the table.

Having conceded that physicians generally do not receive their full charges when transacting with Medicare or private insurers, Udell's insistence that physician charges represent their expectation of payment rings hollow. He even notes that there is a "difference between the expectation of payment and then the reality of payment." (Dkt. No. 443-2 at 23.) In a case involving the determination of hypothetical license damages, the Ninth Circuit explained that a fair market value analysis must be grounded in evidence that reflects actual transactions, noting that to determine the fair market value, "we do not ask what the owner would like to have charged if unconstrained by reality, but what a willing owner actually would have charged after

negotiation with a buyer." *Oracle Corp. v. SAP AG*, 765 F.3d 1081, 1088 (9th Cir. 2014); *see also Colomar v. Mercy Hosp., Inc.*, 461 F. Supp. 2d 1265, 1272 (S.D. Fla. 2006) ("the reality is that the rates hospitals charge for services do not always accurately reflect the value of the services, especially when the hospital routinely accepts much less for them.")

Finally, although Defendants insist that no court has found that a charge-based methodology is improper, many courts actually have considered whether an unpaid hospital bill[3] is admissible as evidence of the market value of physician services, often in the damages context. These courts have uniformly acknowledged that physicians' billed charges do not necessarily reflect the market value of physician services. *See Aetna Life Ins. Co. v. Huntingdon Valley Surgery Ctr.*, 129 F. Supp. 3d 160, 174 (E.D. Penn. 2015) (Chargemaster or price list "rates are not 'actual charges' that providers intend to collect in full from insurers and members; they are (usually) the inflated 'sticker prices' for providers' services that the insurer itself then trims to set the allowed amount) (internal citations omitted); *Howell v. Hamilton Meats & Provisions, Inc.*, 257 P.3d 1130, 1144 (2011) ("[A] medical care provider's billed price for particular services is not necessarily representative of either the cost of providing those services or their market value."); *Corenbaum v. Lampkin*, 215 Cal. App. 4th 1308, 1330–31 (2013) (relying on *Howell* and concluding "that the full amount billed by medical providers for past medical services is not relevant to the value of the services. . . [and] Because the full amount billed for past medical services provided to plaintiffs is not relevant to the value of those services, we believe that the full amount billed for those past medical services can provide no reasonable basis for an expert opinion on the value of future medical services"); *Ochoa v. Dorado*, 228 Cal. App. 4th 120, 135

[3] As defendants have provided no evidence that the charges they relied on were ever actually paid by an individual, a private insurer, or the government, the Court finds it proper to treat the physician charges as unpaid medical bills.

(2014) ("[T]he full amount billed, but unpaid, for past medical services is not relevant to the reasonable value of the services provided."); *Johnson v. Trans-Carriers, Inc.*, 2017 WL 28004 at *2 (D.C.Tenn. 2017) ("The non-discounted charges were not reasonable because they did not reflect the rate for services in the actual marketplace: few insurers pay the hospital's listed, full charge."); *Nassau Anesthesia Assocs. PC v. Chin*, 924 N.Y.S.2d 252, 254 (N.Y. Dist. Ct. 2011) ("Since hospitals and related providers rarely receive payment based upon their 'published rates,' those rates cannot be deemed determinative in assessing the value of the services."); *Temple Univ. Hosp., Inc. v. Healthcare Mgmt. Alternatives, Inc.*, 832 A.2d 501, 510 (Pa. Super. Ct. 2003) ("If the Hospital recovers its published rates in only one to three percent of its cases, those rates clearly do not reflect the amount that members of the community ordinarily pay for medical services.").

b. HHS Has Not Endorsed Udell's Charge-Based Methodology for Determining the FMV of Physician Services

Relying on a single sentence in the Federal Register that follows the guidance on FMV determinations outlined in the legal standards section of this order, the BlueWave Defendants claim that the Government has endorsed Udell's charge-based methodology. The sentence they rely on reads: "there may be cases in which finding a commercially reasonable representation of fair market value (or general market value) could be as simple as consulting a price list." *Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships*, 66 FR 856-01, 944, 2001 WL 7418 (Jan. 4, 2001).

First, there is no evidence that that physician charges Udell relied on reflect the "price" of P&H services, that is, the money expected or required as payment for something. As discussed above, although Udell insists over and over in his deposition that physician charges reflect their expectation of payment, his factual concessions point to the opposite conclusion: that physicians

set their charges higher than the actual payments they expect to receive from Medicare or private insurers.

Second, taken in context with the rest of the Department's guidance about FMV determinations, it is clear that HHS did not intend to suggest that an arbitrary list of figures, totally divorced from the reality of actual transactions, could form the basis of a FMV analysis. For a price list alone to support a FMV determination, it would have to, in some way, reflect the price at which arm's-length transactions are consummated. In any event, the HHS guidance suggests only that there *may be cases* in which consulting a price list is sufficient to assess FMV, and for all the reasons just discussed, this is certainly not one of those cases.

V. Conclusion

For the reasons set forth above, the Government's motion to exclude the expert testimony of Curtis Udell (Dkt. No. 443) is GRANTED.

AND IT IS SO ORDERED.

Richard Mark Gergel
United States District Court Judge

July 11, 2017
Charleston, South Carolina